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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,060	01/03/2002	Frank Frantzen	FRAN3006/REF	1169

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EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,060	FRANTZEN, FRANK	
	Examiner	Art Unit	
	Deborah A. Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the Office Action mailed on March 25, 2003 has been acknowledged. Claims 1-23 have been cancelled and new claims 24-43 have been added and under consideration for examination.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 36 has been renumbered 37 and claims 37-43 has been renumbered 38-44. Also, renumbered claim 38 originally depended from method claim 35. The examiner has corrected the dependency of renumbered claims 38-44 to depend from kit claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 24-43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 24-25 and 36-37 recite the limitation "hapten moieties thereof", which is vague, because it is unclear as to what this term encompasses.

6. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 24-25 recites the broad recitation "sample with two stable aqueous reagents, said reagents together containing a) a polyhapten having S-adenosine homocysteine (SAH) as hapten moieties thereof; b) a first enzyme, being the homocysteine converting enzyme SAH hydrolase; d) a primary antibody, and the claim also recites "wherein said reagents consist of a first reagent comprising said polyhapten, and a second reagent comprising said primary antibody, said first enzyme, which is the narrower statement of the range/limitation.

7. Claims 24 recites contacting said sample with two stable aqueous reagents that comprises a) polyhapten having S-adenosine homocysteine (SAH) as hapten moieties

thereof; b) a first enzyme (SAH) hydrolase and c) a primary antibody capable of binding to said polyhapten, however, this is unclear because there are three aqueous reagents recited and all are in contact directly or indirectly with the sample. If there are only two stable reagents, then applicant does not distinguish which reagents are considered to be stable, therefore, the claim appears to recite three stable reagents.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 24-30, 32-33, 35-39, 41-42,and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Cockbain et al (WO93/15220).

Cockbain et al teaches a method for assaying homocystein in a sample, such as blood, plasma or urine (abstract) which comprises the steps of contacting a sample with a homocysteine converting enzyme (SAH hydrolase) and a SAH (page 6, paragraph 3). The assay of the invention is conveniently uses enzymatic or immunological techniques to detect the analyte in question (page 4, paragraph 5). The sample can also be detected in a sandwich assay that employs a first and second antibody that can be reacted further to form detectable products, as recited in claims 26 (page 9, paragraph 1). Methods based on enzymatic reaction, or reaction with monoclonal or polyclonal antibodies is particularly preferred which may be detected photometrically (page 8,

paragraph 2). To obtain an estimate of the total homocysteine present in the sample, it may be treated with a reducing agent to liberate free homocysteine (page 7, paragraph 4 and page 8, paragraph 1). Beside the use of spectrometric or other photometric techniques, precipitation inhibition or particle agglutination inhibition techniques can be used, which rely on the use of antibody/hapten combinations which on conjugation lead to precipitation or particle aggregation which can be detected by turbidimetric or nephelometric measurement, as recited in claim 27. One of the reagents in the assay appears to be a chaotropic salt (page 17, paragraph 2). The polyhaptens may additionally consist of polymer backbones (page 25, paragraph 1). The kit claims are anticipated by teaching various kit configurations structured for clinical assay use that include reagents such as reducing agents (DTT) with a low buffer and a separate solution of SAH-hydrolase at a neutral PH and preferable buffered. In another embodiment the kit comprises adenosine; s-adenosyl-homocysteine (SAH); anti-S-adenosyl-homocysteine antibody, means for photometrically assessing agglutination or precipitation of antibody: polyhapten complexes and other reagents i.e., polymers (carrier proteins) (pages 23-25).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 34, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cockbain et al in view of Kuroda et al (USP#5,298,397).

The teaching of Cockbain et al are set forth above, but does not particularly point out Porcine thyroglobulin.

However, the reference of Kuroda et al discloses that animal serum albumins and globulins are high molecular weight carriers used in the preparation of the conjugates. The reference provides several examples, which includes rabbit thyroglobulins (column 3, lines 11-24).

It would have been obvious to one of ordinary skill in the art to use known animal serum globulins or albumins as taught by Kuroda in the assay method and kit of Cockbain because they are used in the preparation of antibody hapten conjugates and are high molecular weight carriers.

12. Claims 31 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cockbain et al in view of Baylink et al (USP#5,693,754).

The teaching of Cockbain et al are set forth above, but does not particularly point out PEG.

However, the reference of Baylink et al discloses that polyethylene glycol (PEG) are useful to promote binding and precipitation of assay components (column 4, lines 2-11).

Therefore, it would have been obvious to one of ordinary skill in the art to use a known reagent such as PEG taught by Baylink in the reagents and kit of Cockbain to promote binding of assay components and precipitation of binding complexes for quantitation and qualitative measurements. Further, these reagents are known in the art and are often used in binding assays and other immunological methods.

Response to Arguments

13. Applicant argues that the assay of Cockbain does not anticipate the claims because the assay requires a larger number of reagents of lower stability than could be accepted for such uses. Applicant further argues that there is insufficient teaching present to allow the development of a set of reagents, which could be used in an automated analyzer because the questions of number and stability of reagents are not addressed. These arguments have been fully considered but not found to be persuasive.

In response, the reference of Cockbain teaches the reagents taught by the instant claimed invention. The instant invention used broad comprising language and therefore is not restricted to the use of more reagents. With respect to the argument that Cockbain has insufficient teaching to allow the development of a set of reagents used in an automated analyzer is noted, however, the instant invention is drawn to a assay method and patentable weight is not given to the development of reagents. Therefore, the reference of Cockbain is being maintained.

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis
Patent Examiner
April 20, 2006

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